(1) be subject to judicial review; or

(2) be construed to establish a defense to an enforcement action by the Secretary.

(f) Temporary sunset

Subsection (a) shall cease to be effective on the date that is 5 years after July 9, 2012. Subsections (b), (c), and (e) shall not be in effect during the period beginning 5 years after July 9, 2012, and ending on December 29, 2022. Subsections (b), (c), and (e) shall be in effect beginning on December 29, 2022.

(g) Coordination

The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding—

(1) the reviews of reports shared pursuant to section 374(b)(2) of this title; and

(2) any feedback or corrective or preventive actions in response to such reports.

(June 25, 1938, ch. 675, § 506D, as added Pub. L. 112–144, title X, § 1003, July 9, 2012, 126 Stat. 1103; amended Pub. L. 117–328, div. FF, title III, § 3616(a), Dec. 29, 2022, 136 Stat. 5874.)

Editorial Notes

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, § 3616(a)(2), amended subsec. (f) generally. Prior to amendment, text read as follows: ''Subsections (a), (b), (c), and (e) shall cease to be effective on the date that is 5 years after July 9, 2012.''

Subsec. (g). Pub. L. 117–328, § 3616(a)(1), added subsec. (g).

§ 356e. Drug shortage list

(a) Establishment

The Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States.

(b) Contents

For each drug on such list, the Secretary shall include the following information:

(1) The name of the drug in shortage, including the National Drug Code number for such drug.

(2) The name of each manufacturer of such drug.

(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

(A) Requirements related to complying with good manufacturing practices.

(B) Regulatory delay.

(C) Shortage of an active ingredient.

(D) Shortage of an inactive ingredient component.

(E) Discontinuance of the manufacture of the drug.

(F) Delay in shipping of the drug.

(G) Demand increase for the drug.

(4) The estimated duration of the shortage as determined by the Secretary.

(c) Public availability

(1) In general

Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

(2) Trade secrets and confidential information

Nothing in this section alters or amends section 1905 of title 18 or section 552(b)(4) of title 5.

(3) Public health exception

The Secretary may choose not to make information collected under this section publicly available under paragraph (1) or section 356c(c) of this title if the Secretary determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients).

(d) Interagency notification

Not later than 180 days after March 27, 2020, and every 90 days thereafter, the Secretary shall transmit a report regarding the drugs of the current drug shortage list under this section to the Administrator of the Centers for Medicare & Medicaid Services.

(June 25, 1938, ch. 675, § 506E, as added Pub. L. 112–144, title X, § 1004, July 9, 2012, 126 Stat. 1104; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(G), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 116–136, div. A, title III, § 3112(c), Mar. 27, 2020, 134 Stat. 362.)

Editorial Notes

AMENDMENTS

2020—Subsec. (d). Pub. L. 116–136 added subsec. (d).

2016—Subsec. (b)(3)(E). Pub. L. 114–255, which directed substitution of ''discontinuance'' for ''discontinuation'', was executed by substituting ''Discontinuance'' for ''Discontinuation'' to reflect the probable intent of Congress.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–136 effective 180 days after Mar. 27, 2020, see section 3112(g) of Pub. L. 116–136, set out as a note under section 356c of this title.

§ 356f. Hospital repackaging of drugs in shortage

(a) Definitions

In this section:

(1) Drug

The term ''drug'' excludes any controlled substance (as such term is defined in section 802 of this title).

(2) Health system

The term ''health system'' means a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

(3) Repackage

For the purposes of this section only, the term ''repackage'', with respect to a drug, means to divide the volume of a drug into smaller amounts in order to—

(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list under section 356e of this title; and

(B) facilitate access to the drug by hospitals within the same health system.

(b) Exclusion from registration

Notwithstanding any other provision of this chapter, a hospital shall not be considered an establishment for which registration is required under section 360 of this title solely because it repackages a drug and transfers it to another hospital within the same health system in accordance with the conditions in subsection (c)—

(1) during any period in which the drug is listed on the drug shortage list under section 356e of this title; or

(2) during the 60-day period following any period described in paragraph (1).

(c) Conditions

Subsection (b) shall only apply to a hospital, with respect to the repackaging of a drug for transfer to another hospital within the same health system, if the following conditions are met:

(1) Drug for intrasystem use only

In no case may a drug that has been repackaged in accordance with this section be sold or otherwise distributed by the health system or a hospital within the system to an entity or individual that is not a hospital within such health system.

(2) Compliance with State rules

Repackaging of a drug under this section shall be done in compliance with applicable State requirements of each State in which the drug is repackaged and received.

(d) Termination

This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage.

(June 25, 1938, ch. 675, § 506F, as added Pub. L. 112–144, title X, § 1007, July 9, 2012, 126 Stat. 1106.)

§ 356g. Standards for regenerative medicine and regenerative advanced therapies

(a) In general

Not later than 2 years after December 13, 2016, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

(b) Activities

(1) In general

In carrying out this section, the Secretary shall continue to—

(A) identify opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

(2) Regulations and guidance

Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

(c) Definitions

For purposes of this section, the terms ''regenerative medicine therapy'' and ''regenerative advanced therapy'' have the meanings given such terms in section 356(g) of this title.

(June 25, 1938, ch. 675, § 506G, as added Pub. L. 114–255, div. A, title III, § 3036, Dec. 13, 2016, 130 Stat. 1104; amended Pub. L. 115–52, title IX, § 901(b), Aug. 18, 2017, 131 Stat. 1076.)

Editorial Notes

AMENDMENTS

2017—Subsec. (b)(1)(A). Pub. L. 115–52 substituted ''identify'' for ''identity''.

Statutory Notes and Related Subsidiaries

GUIDANCE REGARDING DEVICES USED IN THE RECOVERY, ISOLATION, OR DELIVERY OF REGENERATIVE ADVANCED THERAPIES

Pub. L. 114–255, div. A, title III, § 3034, Dec. 13, 2016, 130 Stat. 1103, provided that:

''(a) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the 21st Century Cures Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance clarifying how, in the context of regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the Secretary shall specifically address—

''(1) how the Food and Drug Administration intends to simplify and streamline regulatory requirements for combination device and cell or tissue products;

''(2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device;

''(3) when the Food and Drug Administration considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and

''(4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.